Patent
Case No.: 48317US032

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	JAPUNTICH, DANIEL A.		
Application No.:	09/837714	Group Art Unit:	3761
Filed:	April 18, 2001	Examiner:	Aaron J. Lewis
Title:	METHOD OF MAKING A FILTERING FACE MASK THAT HAS AN EXHALATION VALVE		

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING
I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

August 25, 2003
Date

Signed by: Susan M. Dacko

Dear Sir:

This is an appeal from the Office Action mailed on March 26, 2003. This Brief is being filed in triplicate. The fee required under 37 CFR § 1.17(c) for the appeal should be charged to Deposit Account No. 13-3723.

A separate Amendment, which changes the title, is included with this Brief.

I. REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

II. RELATED APPEALS AND INTERFERENCES

The following related applications are currently on appeal: 08/240,877, 09/678,579, and 09/678,580.

III. STATUS OF CLAIMS

Claims 33, 35-42, 44, 46, 49, 50, 55-59, and 64-66 are pending in this case and are the subject of this appeal. Claims 39 and 40 have been indicated as being allowable if rewritten in independent form.

IV. Status Of Amendments

No amendments have been filed after the final rejection. An amendment filed after the final Office Action was not entered in this case.

V. Summary Of The Invention

Persons who work in contaminated environments commonly wear filtering face masks over their nose and mouth to protect themselves from inhaling airborne pollutants. Many known filtering face masks have employed a cup-shaped mask body that includes a filter layer and that is adapted to fit over a wearer's nose and mouth. Exhalation valves have been used on these masks to rapidly purge exhaled air from the mask interior. The rapid removal of exhaled air makes the mask more comfortable to wear.

Because exhalation valves are powered by the wearer's lungs, valves that open easier during each exhalation improve wearer comfort because less work is needed to operate the valve. Valves that open easier also are beneficial in that they purge warm, moist, exhaled air more rapidly from the mask interior. In the working examples of the present invention, the applicants demonstrated that they were able to remove so much air (>100%) from the mask interior during a simulated exhalation, that an influx of cool ambient air occurred during the exhalations (see Table 2, particularly Examples 11-13). For filtering face masks that have porous mask bodies, this is quite an achievement because it demonstrates, for the first time, that a filtering face mask can operate as a cool-air aspirator — drawing cool, low humidity, air into the mask interior through the filter media to substantially improve wearer comfort. No prior art exhalation valve on a filtering face mask had yet demonstrated such a feat during an exhalation.

The most common type of exhalation valve that has been used on a filtering face mask is a "button-style" valve. These valves typically have a circular flexible flap that is mounted to a valve seat through a central stake or button. The whole circumference of the flap is generally free to be lifted from the seal surface during an exhalation. An example of a button-style valve is shown from the side in Figure 3 of UK patent application GB 2,072,516A to Simpson:

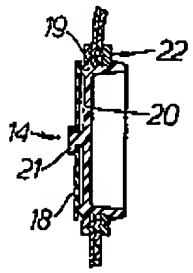


FIG. 3.

[Simpson Button-Style Valve]

Another example of a button-style valve is shown in U.S. Patent 4,873,972 to Magidson et al., assigned to Moldex/Metric Products Inc. and issued on October 17, 1989.

In addition to button-style valves, other valve structures have been used to purge exhaled air from the mask interior. For example, U.S. Patent 4,934,362 to Braun describes a valve, which when viewed from the side, has a parabolic valve seat. Like the button-style valves, the Braun valve has its flap mounted centrally to the valve seat:

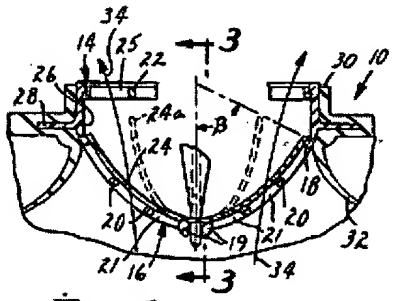


FIG. 2

This central mounting, however, can interfere with the flow of exhaled air through the valve and does not allow as great a moment arm to be achieved in lifting the flap from the seal surface. Centrally-mounted valves also can cause exhaled air to be diverted into multiple flow streams.[1]

As an alternative to these centrally-mounted valves, a "flapper-style" or "cantilevered" valve also had been disclosed as being suitable for use on filtering face masks. Figure 2 of the Simpson patent shows such a valve:

[1] Examples 4-6 in applicants' specification show the performance of the Braun valve compared to applicants' invention.

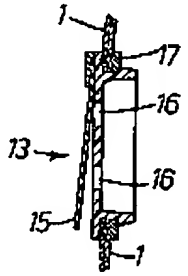


FIG. 2.

[Simpson Flapper Valve]

This flapper-style valve includes a "flexible circular flap member 15 of, for example, plastics material, which is arranged to cover and close valve opening 16 during an inhalation and to flex away from those openings during exhalation." To enable the flap member to flex, "a part of its peripheral portion, a segment of the flap member, is fixed in position, the remaining part of the flap member being left free." See Simpson at page 2, lines 37-46.

Although Simpson's flapper-style valve can provide a greater moment arm in lifting the flap 15 from the seal surface to encourage quick displacement of exhaled air from the mask interior, the valve does suffer from a number of deficiencies, amongst them, the inability to keep the flap closed under any orientation of the valve. To apparently keep its valve closed under neutral conditions — that is, when a wearer is neither inhaling nor exhaling — Simpson mounts the valve 12 on the top portion 1 of its duck-billed mask:

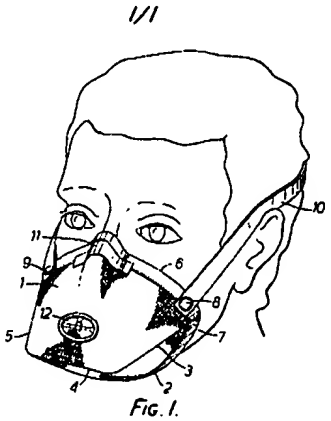


FIG. 1.

[Simpson Mask]

Simpson does not describe how to construct a flapper-style valve where the flap is pressed against a seal surface when a wearer is neither inhaling or exhaling. Simpson's valve relies on gravity for this purpose. This reliance on gravity, however, places limits on the locations where

Simpson's valve could be disposed on a cup-shaped mask without risking an influx of contaminants into the mask interior when a wearer is neither inhaling nor exhaling. And when the valve is not disposed directly in (or normal to) the path of the exhaled flow stream, the flap cannot fully take advantage of the momentum of the exhale flow stream during an exhalation to encourage more rapid and complete opening of the valve. Without this ability, displacement of exhaled air cannot be maximized, and aspiration effects are less likely to occur. In addition, because the Simpson valve does not have a pre-load on it, there is a great risk that the valve could remain open. Saliva and moisture commonly builds up on exhalation valves during use. The presence of these substances on the flap can cause the it to stick to another surface such as a valve cover when the flap comes open as a result of a force from an exhalation, or in Simpson's case from mere gravity. If the valve stays open, then contaminants can be directly drawn into the wearer's respiratory system during the next inhalation. Simpson recognizes that its valve may leak and suggests the use of an "antechamber" to prevent inhalation of "harmful atmosphere". See Simpson at p. 1 lines 58-64.

Applicants' method includes supporting a flap 24 differently on the valve seat 26 to provide a mask that exhibits better in performance over known exhalation valves:

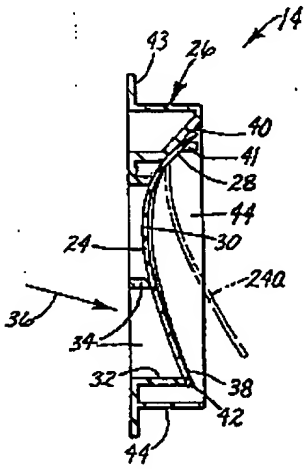


Fig. 3

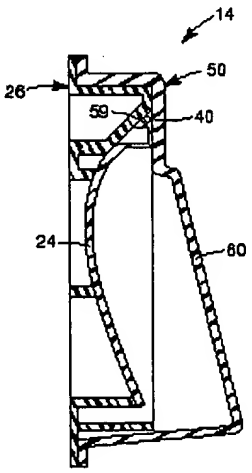


Fig 8

[Applicants' Valve]

In applicants' invention, the single flexible flap 24 is supported non-centrally and operatively relative to the orifice 32 of the valve seat 26 to form an exhalation valve 14. The single flexible flap 24 is supported such that: (i) the flexible flap 24 has, in its closed state, an imposed curved

profile in a cross-sectional side view thereof, which imposed curved profile extends from a first point where a stationary portion 28 of the flexible flap 24 is supported on the valve seat 26 to a second point where a free portion 38 of the flexible flap 24 contacts the seal surface 31; (ii) the free portion 38 of the flexible flap 24 is pressed towards the seal surface 31 of the valve seat 26 in a closed state of the exhalation valve 14 under any orientation thereof; (iii) the free portion 38 of the flexible flap 24 is held in the closed state under any orientation of the valve 14, at least in part, by virtue of the imposed curved profile thereof; and (iv) the free portion 38 of the flexible flap 24 represents the only free portion of the flap 24 and can flex away from the seal surface (as shown in Figure 3 with reference numeral 24a) so as to permit exhaled air 36 to pass through the orifice 32 and to provide an open state 24a of the exhalation valve 14 to make the flexible flap 24 out of contact with the seal surface 31 at the second point while the stationary portion 28 of the flexible flap 24 remains essentially stationary at the first point.

The new method of supporting the flap non-centrally and operatively relative to the orifice enables an imposed curved profile to be imparted to the flap and hence causes the flap to be pressed against the seal surface 31, under any orientation of the valve, when no fluid is passing through the flap. Although pressed against the seal surface to prevent the unwanted influx of contaminants, the flap's one free portion 38 can be readily lifted from the seal surface during an exhalation (as a bent cantilever) to allow large quantities of air to be rapidly purged from the mask interior (see applicants' specification at page 6, line 25 to page 9, line 29; see also Examples 4-13).

Although the resultant different structure and benefits of applicants' invention have not been taught in the prior art, they have, however, been utilized by investigators in this field after publication of applicants' invention. For example, the Louis M. Gerson Company introduced a mask in approximately March of 2001 (see McGinley Affidavit at paragraph 4.h.; copy attached as file Exhibit F — a sample of the Gerson mask is attached to this Appeal Brief as Exhibit G). The Gerson mask uses a flapper-style valve where a curved flap is positioned relative to the orifice to be pressed towards the seal surface under any orientation of the mask. Before publication of applicants' invention, Gerson sold masks that used button-style valves. In addition, Magidson — an inventor of the subject matter used in the '972 Moldex patent mentioned above — described the use of a button-style valve on a filtering face mask in a 1988 patent application. But after the publication of applicants' invention, Magidson (in U.S. Patent

6,047,698 to Magidson et al. also assigned to Moldex-Metric Inc. and filed on August 20, 1998) described a flapper-style valve that supports the flexible flap non-centrally and operatively relative to the orifice such that the flap is curved and is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve:

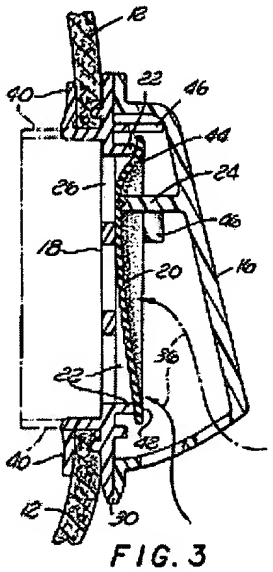


FIG. 3

[Magidson Valve]

Thus, while investigators in the pertinent field did not appreciate applicants' new method before it was published, these same investigators did choose to adopt it once it became publicly known.

VI. Issues On Appeal

Issue - Obviousness

Applicants' independent claims 33, 65, and 66 have been rejected based on a combination of GB 2,072,516A to Simpson and U.S. Patent 3,191,618 to McKim. Simpson describes a flapper-style exhalation valve for a filtering face mask that operates under temperatures and pressures generated by a human's respiratory system and at a person's breathing pace (typically 20 to 60 cycles per minute), but McKim describes a curved seat reed valve for a 2-cycle engine that would operate at internal combustion temperatures and pressures and at speeds on the order of 10,000 or 12,000 revolutions per minute (rpms). McKim's reed valve is made of rigid spring sheet material such as shim stock. Would Simpson and McKim have rendered the subject matter of claims 33, 64, and 65 obvious to a person of ordinary skill under the terms of 35 USC § 103?

VII. GROUPING OF CLAIMS

The independent appealed claims will stand or fall as separate claims while the dependent claims will stand or fall with the subject matter of the claims from which they depend. No admission, however, is being made with respect to the obviousness of the subject matter of the dependent claims with respect to the subject matter of the independent claims.

VIII. ARGUMENTS OF APPLICANTS

Issue - Obviousness Based on Simpson and McKim

1. Applicants' Invention

Applicants' invention pertains to a method of making a face mask 10 that comprises (a) a mask body 12 that is adapted to fit over the nose and mouth of a person and (b) an exhalation valve 14 that may be attached to the mask body 12 directly in front of where the wearer's mouth would be when the mask is worn:

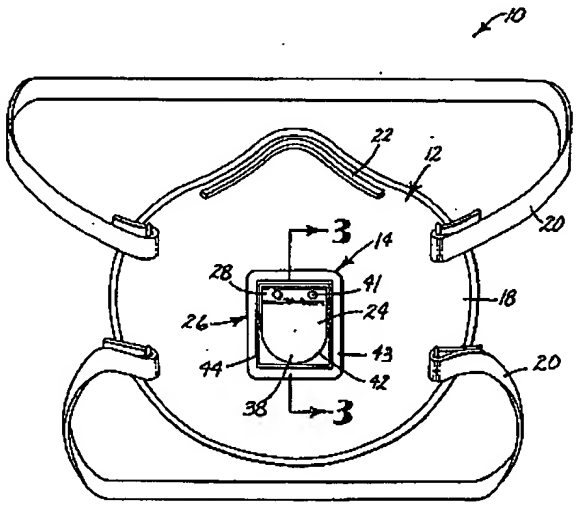


Fig. 1

[Applicants']

In applicants' method, the flexible flap is supported differently on the valve seat 26 to enable the mask to exhibit better performance over known exhalation valves:

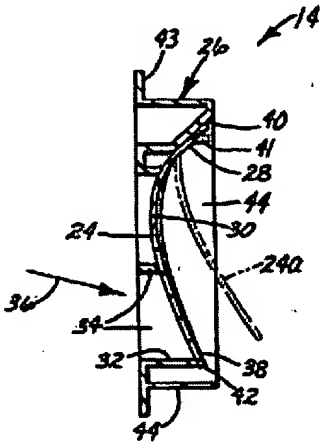


Fig. 3

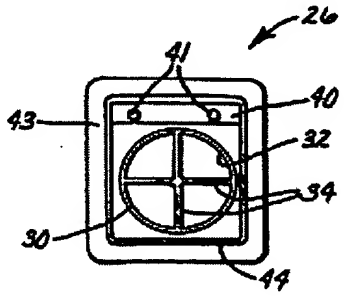


Fig. 4

[Applicants']

The single flexible flap 24 is supported non-centrally and operatively relative to the orifice 32 of the valve seat 26 to form an exhalation valve 14. The single flexible flap 24 is supported such that: (i) the flexible flap 24 has, in its closed state, an imposed curved profile in a cross-sectional side view thereof, which imposed curved profile extends from a first point where a stationary portion 28 of the flexible flap 24 is supported on the valve seat 26 to a second point where a free portion 38 of the flexible flap 24 contacts the seal surface 31; (ii) the free portion 38 of the flexible flap 24 is pressed towards the seal surface 31 of the valve seat 26 in a closed state of the exhalation valve 14 under any orientation thereof; (iii) the free portion 38 of the flexible flap 24 is held in the closed state under any orientation of the valve 14, at least in part, by virtue of the imposed curved profile thereof; and (iv) the free portion 38 of the flexible flap 24 represents the only free portion of the flap 24 and can flex away from the seal surface (as shown in Figure 3 with reference numeral 24a) so as to permit exhaled air 36 to pass through the orifice 32 and to provide an open state 24a of the exhalation valve 14 to make the flexible flap 24 out of contact with the seal surface 31 at the second point while the stationary portion 28 of the flexible flap 24 remains essentially stationary at the first point. The exhalation valve is attached to the mask body such that the first point is disposed above the second point when the mask is viewed from the front in an upright position.

2. The Simpson Patent

Simpson describes a flap valve 13 with reference to its Figure 2, which valve comprises a flexible circular flap member 15:

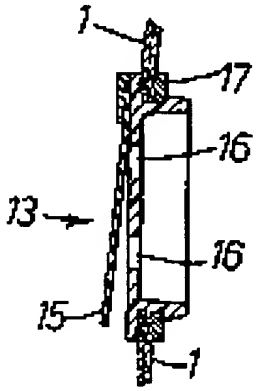


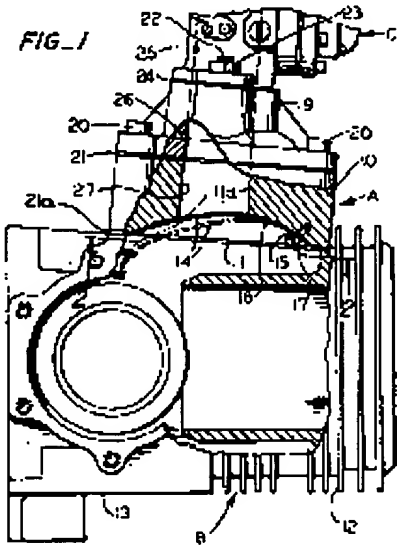
FIG. 2.

[Simpson]

The flap member 15 is made of a plastic material and is arranged to cover a closed valve opening 13 during an inhalation and to flex away from those openings during an exhalation (p. 2, lines 37-42). To allow flexing of the flap member 15, a part of its peripheral portion — that is, a segment of the flap member — is fixed in position and the remaining part of the flap member is left free (p. 2, lines 42-46). The valve is fitted in an aperture on the mask and is held in place by a retaining ring 17 (p. 2, lines 46-50). As shown in Simpson's Figure 1 reproduced above, the valve 12 is disposed on the top portion 1 of Simpson's duck-bill or pouch-shaped mask.

3. The McKim Patent

McKim discloses a curved seat reed valve for a 2-cycle engine:



[McKim]

The reed valve includes a valve reed 14 of spring sheet materials such as shim stock (col. 1, lines 60-61). The spring sheet material is secured by an anchor bar 15 and screws 17 to a curved seat 18 that is formed on the inner-engine side of the valve bock 10 (col. 1, lines 61-63). Curvature of the seat 18 corresponds to the normally flexed condition of the valve reed 14 when it is flexed laterally from its normally straight position as shown in Figure 3 (col. 1, lines 64-66). The normally flexed curvature of the reed is provided to eliminate float, or flutter from bounce when closing (column 1, lines 19-24; column 2, lines 55-62). The McKim valve is fashioned for use on high-speed engines, for example, one that will turn at a speed on the order of 10,000 to 12,000 revolutions per minute (col. 2, lines 55-62). For a more modest speed, for example, 5,000 or 6,000 rpms, the curvature of the valve seat may be reduced to provide a freer, fuller opening of the valve at the lower speeds (column 2, lines 62-65).

4.0 Reasons for Nonobviousness

The Simpson and McKim combination of documents would not have made appellant's invention obvious to a person of ordinary skill for the following reasons.

4.1 Simpson Falls Short of Teaching Applicants' Invention

Firstly, the subject matter of applicants' invention is structurally and functionally dissimilar to the subject matter described in Simpson. Simpson does not describe a structure that exhibits a pre-stress on the flap. When closed, the Simpson flap remains flat in planar alignment with its flap-

retaining surface and seal surface. An expert in the field of respirators and respirator components, David M. Castiglione, has provided evidence that establishes that the valve 13 shown in Figure 2 of the '516 U.K. Patent Application (Simpson) does not have its flap 15 *pressed* against the seal surface in an abutting relationship with it when a wearer would be neither inhaling nor exhaling. Castiglione states in paragraph 9 of his February 2, 2001 Affidavit (Exhibit A)[2] that "there is nothing that can be discerned from Figure 2 [of Simpson] or from the [Simpson] specification that would indicate that the flap is pressed towards the seal surface in its neutral position." Another expert in the field of exhalation valves, John Bowers, (the inventor named in U.S. Patent 5,687,767) stated the following with respect to Simpson in paragraph 15 of his Declaration dated December 10, 2001 (Exhibit B):

> My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.

Given the aligned relationship between the flap retaining surface and the seal surface, there is no force exerted upon the flap that would bias the flap against the seal surface. The flap 15 can only reside in mere contact with the seal surface in the closed position. Simpson therefore places the exhalation valve 12 on the top portion 1 of its pouch-shaped mask (see Fig. 1 of Simpson) so that gravity can hold the valve shut when the wearer is neither inhaling nor exhaling. Gravity, however, cannot *support the flap non-centrally and operatively relative to the orifice such that the second free portion of the flap is pressed against the seal surface of the valve seat in a closed state of the exhalation valve and such that the second free portion of the flexible flap is held in its closed state under any orientation of the valve, at least in part, by virtue of the curved profile thereof.* Gravity also does not induce a curved profile to the flap while it is in contact with the seal surface. Simpson does not teach or suggest such a mask because, as indicated, its flap is mounted

[2] Exhibits A-F can be found attached to the Amendment mailed on June 25, 2002.

with no pre-stress and therefore is located on the top of the mask to utilize gravity to keep the valve closed.

4.2 McKim is Non-Analogous Art

Secondly, the secondary reference, U.S. Patent 3,191,618 to McKim, cannot be applied as a reference against applicants' invention because the McKim patent does not describe analogous art. As the Board is aware, a reference cannot be considered sufficiently analogous and thus relevant for determining obviousness unless it is either (1) within the field of the inventor's endeavor, or (2) is reasonably pertinent to the particular problem that confronted the inventor.[3] Applicants' invention resides in the field of filtering face masks that use exhalation valves. McKim does not reside within this field of endeavor: it resides in the field of gasoline engines that use reed valves.

McKim shows a curved seat reed valve that is designed for use in a 2-cycle engine, which would turn at speeds as high as 10,000 or 12,000 revolutions per minute. In contrast, applicants' invention pertains to a filtering face mask that employs an exhalation valve, which opens in response to a wearer's breathing. Castiglione explained in his November 15, 1999 Affidavit (Exhibit C) why McKim does not reside in the field of endeavor of applicants' invention:

> The field of endeavor for a filtering face mask is very different from the field of endeavor of a curved seat reed valve that is used in a high-speed engine. Persons of ordinary skill in the field of designing filtering face masks do not consult documents that describe valves for gasoline engines in developing respiratory products. Exhalation valves for respirators operate under very different conditions from valves that are used in gasoline engines and require extraordinary different design parameters.

Another investigator who works in the filtering face mask field, John L. Bowers, explains in more detail why McKim is not in the field of endeavor of a person of ordinary skill in the art designing exhalation valves:

> My review of the McKim patent shows a curved seat reed valve that is designed for use in a high-speed engine, which could turn at speeds as possibly as high as 10,000 or 12,000 revolutions per minute (rpm). The reed valve described in McKim is indicated to be particularly suited for a high speed operation where opening and closing forces are large. McKim states these forces can cause the valve to bounce (an apparent elastic recoil from impact). The stated goals in

[3] *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992).

McKim are full and rapid opening, quick and complete closing, and eliminating float and bounce.

The field of the above-captioned '877 invention pertains to a filtering face mask that employs an exhalation valve. A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in the ambient air. Filtering face masks commonly employ exhalation valves to allow warm, moist, exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves generally operate at normal room temperatures and pressures.

The field of endeavor for filtering face mask is very different from the field of endeavor of a reed valve that is used in a two-cycle engine. Exhalation valves for respirators operate under very different conditions from valves that are used in two-cycle engines and require notably different design parameters. The valve that is described in McKim has very rapid opening and closing requirements (thousands of openings and closings per minute) and operates under temperatures and pressures that differ substantially from the requirements of exhalation valves, which open and close under the much slower pace of a wearer's breathing and under temperatures and pressures that tend to vary only from the ambient to that exhibited by the wearer's exhaled air. Thus, persons of ordinary skill in the field of designing filtering face masks, to the best of my knowledge and experience, do not find valves for two-cycle engines to be in their field of endeavor and therefore do not consult documents that describe valves for these engines when developing new respiratory products.

Bowers' Affidavit, paragraphs 11-13 (Exhibit B). Another person skilled in the field of exhalation valves for filtering face masks, Frank Fabin, who has worked on one design team and led another design team in the development of a new exhalation valve, stated the following with respect to McKim:

My review of the McKim patent reveals a curved seat reed valve that is suitable for use in high rpm two-cycle engines. The reed valve comprises a thin, normally flat, single thickness, springy, sheet material, which, when relieved of external stresses will lie flat, but which is flexed lengthwise to define a curve. The reed valve is disclosed to be made of a spring sheet material, such as, for example, shim stock. The reed valve is disclosed to bear throughout its length against a valve seat, with the seating bias at the free end of the reed being as great as, or greater than, that throughout the remainder of the reed. The reed valve is indicated to be designed to seat quickly, effectively, and without float or bounce after each opening. The patent indicates that the reed valve is adaptable for use within an extremely high-speed engine, for example, one that will turn at a speed on the order of 10,000 or 12,000 revolutions per minute or at more modest speeds of 5,000 to 6,000 rpms.

In my approximately 24 years of working in occupational health, I have not — nor am I aware of another person who works in this field who has — consulted a

> reference in the reed valve art for gasoline engines to obtain solutions to problems encountered in developing exhalation valves that are used on filtering face masks.
>
> Filtering face masks posses the problem of creating a warm, moist, high CO_2 content environment around the nose and mouth of a person who wears a filtering face mask. Investigators in this field have pursued a goal of purging from the mask interior the largest amount of fluid possible while using the least amount of energy. Investigators therefore have pursued the particular goal of designing exhalation valves that open easily in response to the exhalation pressure developed in the mask interior during an exhalation. Exhalation valves that open under minimal pressure allow the warm, moist high CO_2 content air, to be more easily removed from the mask interior and thus require the wearer to expend less energy to operate the valve over an extended period of time. Exhalation valves typically operate under ambient environmental conditions in response to exhalation pressures generated by the wearer. These conditions are remarkably different from the environment (for example, temperatures and pressures) under which a reed valve operates in a two-cycle gasoline engine. The flexible flaps that are used in exhalation valves do not deal with problems of float, or flutter from bounce in closing like the reed valves described by McKim. The opening and closing of an exhalation valve occurs in cadence with a wearer's breathing pace, which is orders of magnitude less than the high rpms under which gasoline engines operate at. For these reasons and others, persons of ordinary skill in the filtering face mask and exhalation valve art, as far as I am aware, do not examine documents that pertain to reed valves for two-cycle gasoline engines in designing filtering face masks and the exhalation valves that are used on them. Documents that describe reed valves for two-cycle gasoline engines are not in the field of endeavor of persons who design exhalation valves for filtering face masks.

Fabin Affidavit, paragraphs 8-10 (December 10, 2001) (Exhibit D). In view of this evidence, it is clear that McKim does not reside in the field of endeavor of a person who designs exhalation valves for use on filtering face masks. Because the Examiner has not put forward any evidence to the contrary, the only conclusion that can be reached is that McKim is not in applicants' field of endeavor.

Since the first element of the two-part test for evaluating whether a reference is analogous has not been satisfied, it therefore is necessary to consider whether the McKim reference is reasonably pertinent to the particular problem that concerned applicants. The Federal Circuit has explained that the USPTO needs to consider the purposes of the reference disclosure and the invention in determining whether a reference meets the second prong of the two-part test:

> A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in

> considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his intention. **If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it** (emphasis added).[4]

In developing their invention, applicants sought to produce an exhalation valve that minimized exhalation pressure needed to open the valve and allowed a greater percentage of exhaled air to be purged through the exhalation valve to improve wearer comfort (see applicants' specification at page 3, line 25 to page 5, line 34 and Examples 4-6 and 8-13). The McKim reference, however, deals with solving the problem of float or bounce, which may occur when a 2-cycle engine is operating at high rpms (see McKim at column 1, lines 20-24 and column 2, lines 55-62). McKim's concern for controlling float or bounce is not reasonably pertinent to the problems that applicants were involved with — namely, providing comfort to the mask wearer by allowing the valve to open under minimal pressure and enabling a greater percentage of exhaled air to be purged through from the mask interior through the valve. As stated in the Bowers Declaration, investigators who work in the field of exhalation valves for filtering face masks are not concerned with problems of float or bounce:

> In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would

[4] *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992).

> not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

The Castiglione and Fabin declarations discussed above also explain how McKim is concerned with a problem that is of no concern to the purpose of the present invention. Because the purpose of applicants' invention is not pertinent to the problem that McKim dealt with, namely float or bounce, the second prong of the test for qualifying as an analogous reference also has not been met. A person possessing ordinary skill in the art of filtering face masks that use exhalation valves would not reasonably have been expected to solve the problem of lowering the airflow resistance force needed to open an exhalation valve through considering a reference that deals with eliminating float or bounce in a valve reed in a 2-cycle gasoline engine.

With respect to the evidence that applicants have presented regarding whether McKim is analogous, the Examiner states that:

> As to the Bowers, Fabin, Castiglione and Betts affidavits, the individual arguments that McKim constitutes nonanalogous art because it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, it is submitted that one of ordinary skill would look to the art of valves (which includes McKim ('618)) to address problems associated with the effectiveness of valve seating of a valve element which is used for controlling the direction of flow of breathable air through such a valve. McKim clearly addresses the problem of effectiveness of valve seating by non-aligning the flap retaining surface and the seal surface relative to each other thereby providing effective seating without float or bounce after each opening (col. 1, lines 64-72).

Applicants respectfully assert that the Examiner is incorrect in finding the facts and is incorrect in applying the law. Firstly, the record does not reflect any evidence of a desire to provide "effective seating without float or bounce after each opening" of an exhalation valve. As applicants have demonstrated repeatedly during this prosecution, this position is merely a statement of his opinion, wholly unsupported by any evidence of record. Nowhere does the

record show that "float or bounce" is a problem that needs to be overcome in the exhalation valve art. In fact, the evidence of record establishes the exact opposite: it shows that "float or bounce" is not a problem that needs to be dealt with by persons who design exhalation valves. Secondly, the second part of the two-part test for determining whether a reference is analogous does not look only at the purpose of the device described in the cited reference. The test looks at the purposes of **both** the claimed invention and the device described in the prior art document, and it compares these two purposes.[5] The Examiner has not examined both purposes and has not made such a comparison. The Examiner therefore has committed legal error by only examining the purpose of McKim.

In the leading case that deals with "analogousness" under part (2) of the test, the Federal Circuit has explained that the USPTO needs to consider the purposes of the reference disclosure *and* the invention in determining whether a reference is reasonably pertinent to the particular problem that confronted the inventor.[6] In *In re Clay*, the Federal Circuit found the cited reference to be not analogous when (1) the prior art taught the use of a gel within a natural, underground, oil-bearing formation to channel flow in a desired direction and (2) the applicant, Clay, had invented the use of a gel to fill the confined dead volume of a man-made storage tank. Although the inventor Clay and the prior art (Sydansk) both described technology that related to the use of gels in the petroleum industry, *the prior art Sydansk reference was found to be nonanalogous because the purpose of the Sydansk teachings were different from the purpose of the Clay invention*. Sydansk was faced with the problem of recovering oil from rock, which was not pertinent to the problem with which Clay was involved, namely, preventing loss of stored product in a tank's dead volume. The court also recognized that the subterranean formation of

[5] Because the Examiner does not dispute the fact that McKim does not reside in applicants' field of endeavor, we only need to evaluate McKim under part (2) of the test.

[6] *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his intention. **If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it** (emphasis added)")

Sydansk was not structurally similar to and did not operate under the same temperature and pressure and did not function like Clay's storage tanks.[7]

As in *In re Clay*, the McKim reference also does not have the same purpose as applicants' invention, it does not operate under the same temperature and pressure, and it does not function like the claimed invention. Float or bounce is a problem that occurs when 2-cycle engines operated at high rpms (10,000 to 12,000 rpms). It has not been a problem that occurs in exhalation valves, which open and close in cadence with a person's breathing, about 20 to 60 cycles per minute. In addition, internal combustion engines operate at extraordinarily higher temperatures and pressures than a person's exhalation breath and are not powered by a person's lungs but by gasoline combustion. Finally, McKim's valve is used for intake into a combustion cylinder while the present valve is used for exhaust from the interior gas space of a mask.

Applicants accordingly encourage the Board to consider the *In re Clay* decision in light of the present rejection.[8] A summary of the facts in *In re Clay* are provided below for ease of reference:

[7] *See, Clay*, 23 USPQ2d at 1601 ("Moreover, the subterranean formation of Sydansk is not structurally similar to, does not operate under the same temperature and pressure as, and does not function like Clay's storage tanks.").

[8] *See also, SRI Int'l, Inc. v. Advanced Tech. Lab.*, 45 F.3d 443, 445 (Fed. Cir. 1995) ("The problem Green solved was how to compensate for changes in the spectral distribution of the return ultrasonic signal, with time or depth of penetration into a living organ, for enhanced image resolution and/or signal to noise ratio. The Minton reference, which relates to seismic prospecting circa 1946, almost thirty years prior to Green's filing date, would not have logically commended itself to Green's attention in considering how to compensate for changes in the spectral distribution of a received ultrasonic signal in an object such as a body part."); *In re Green*, 22 F.3d 1104, 1105 (Fed. Cir. 1994) ("A person of ordinary skill in the aircraft vane art simply would not find a 1919 reference about broken blades in a pugging mill reasonably pertinent to this problem."); *In re Butera*, 1 F.3d 1252, 1253, 28 USPQ2d 1399, 1400 (Fed. Cir. 1993) ("Butera's design is for air fresheners and insect repellents, while Hodge's is for metal ball anodes. The design of Hodge involves a different type of article from Butera's design and it is not analogous. One designing a combined insect repellent and air freshener would therefore not have reason to know of or look to a design for a metal ball anode. Since Hodge is not analogous, the Board clearly erred in finding Hodge to be citable as prior art. Therefore there was no basis for rejecting Butera's claimed design as obvious."); *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 864, 26 USPQ2d 1767, 177_ (Fed. Cir. 1993) ("Wang's SIMMs were designed to provide compact computer memory with minimum size, low cost, easy repairability, and easy expandability. In contrast, the Allen-Bradley patent relates to a memory circuit for a larger, more costly industrial controller. SRAMs were used by Allen-Bradley because of their intended industrial environment. According to Dr. Frey, size was not a consideration in the Allen-Bradley work. Thus, there is substantial evidence in the record to support a finding that the Allen-Bradley prior art is not reasonably pertinent and is not analogous.").

In re Clay	**Result: reference <u>not</u> analogous**					
	Description	***Problem to be Solved***	***Purpose***	***Operating Conditions***	***Similarities***	***Differences***
Clay	use of gel to displace liquid product from tank dead volume	preventing loss of stored product to tank dead volume	to displace liquid product from dead tank volume	• subterranean rock • high temps (115°C) and bore pressures	both used in petroleum industry	different purposes and operating under different temperatures and pressures
Prior Art Sydansk	use of gel to fill anomalies in natural oil-bearing conditions	recovering oil from rock	to channel flow in a desired direction	• made storage tank • ambient temp and pressure		
In re Japuntich et al.	**Result: not yet decided**					
Applicants' Invention	use of a new flapper-style exhalation valve in a filtering face mask	keeping valve closed under any orientation while allowing low pressure drop during an exhalation	to allow valve to open easier during an exhalation but remain closed under neutral conditions	• exhale valve on face mask body • body temperatures • low pressures • cadence of person's breathing	both relate to valves	different purposes and operating under different temperatures, pressures, and speeds
McKim	use of new reed intake valve in a two-stroke engine	stopping flutter or bounce of reed valve while operating under high RPM conditions	to eliminate float or bounce of valve reed to improve power and efficiency of engine	• intake valve on 2-cycle engine • high temps • high pressure • high speeds (10-12,000 rpms)		

The Federal Circuit has stated that when the reference "is directed to a different purpose [than the applicants' invention], the inventor would accordingly have less motivation or occasion to consider it" and therefore it would not be analogous.[9] Because the Examiner only considered the purpose of McKim's valve in evaluating whether it was analogous but did not consider the purpose of applicants' invention and compare it with McKim's purpose, the Examiner has erred in determining that McKim is analogous. This error, in turn, has caused the Section 103 rejection to be improperly maintained.

[9] *Id.*

4.3 McKim's Flap is Not Flexible

Thirdly, even if McKim was found to be an analogous reference, a person of ordinary skill still would not have been led to applicants' invention because the structure of the reed valve disclosed in McKim would not answer the required properties of applicants' valve. There is no evidence that the McKim reed valve would demonstrate the required flexibility of applicants' flexible flap. Applicants have defined the term "flexible" to mean that "the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation (see, e.g., Fig. 5)."[10] The flap that is described in McKim is made of "spring sheet material, such as, for example, shim stock" (column 1, lines 59-61). McKim therefore is not describing a flexible flap that would be suitable for use in an exhalation valve. This fact is confirmed by Richard Betts, a person skilled in the art of two-cycle engines:

> Since 1965, the 2-cycle engines that I have either constructed or worked on have used a reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, were "flexible" as the term has been defined in the above-captioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to a force such as shown in Fig. 3 of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the mere force of gravity. If the valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than the flexible flaps that are used on exhalation valves.

Declaration of Richard Betts, paragraph 5 (December 7, 2001) (Exhibit E). Because McKim's valve reed is so structurally different from the flexible flap that is used in the present invention, there would be no reason to expect — and there is no evidence in this record to indicate otherwise — that McKim's method of mounting its stiff valve reed would be suitable for a more highly flexible flap that is used on an exhalation valve. Further, the conditions under which the McKim reed valve operates (high pressure, high temperatures, 10,000 or so cycles per minute) is so remarkably different from the conditions under which an exhalation valve operates (lung pressure,

[10] Applicants' specification at page 7, lines 11-14.

exhaled air temperatures, and breathing cycles of 20-60 per minute), that there can be no expectation that any structure described in McKim would be suitable to produce an invention like the one under consideration here. Thus, the mounting requirements for the McKim cannot be transferred to an exhalation valve like Simpson's without some clear teaching or suggestion to do so. The Examiner, however, discards this argument because Simpson describes a flexible flap:

> Applicant's argument that the valve of McKim lacks the required flexibility of applicant's invention is noted; however, it is submitted that the valve of Simpson et al., being an exhalation valve, exhibits structure which is fully capable of providing such a function.

The Examiner's remarks are nonresponsive and are legally erroneous in that they, respectively, ignore the thrust of applicants' position and only restate the presence of the elements of applicants' invention in the art without showing any evidence of why the combination would have been made. Applicants contend that McKim's teachings cannot be combined with Simpson because there would be no reason to expect — and there is no evidence in this record to indicate otherwise — that McKim's method of mounting its stiff valve reed would be suitable for a more flexible flap that is used on an exhalation valve. Applicants thus argue that teachings that pertain to a very rigid piece of metal (McKim's shim stock valve) cannot be applied to a valve that has a highly flexible plastic material (Simpson valve flap) without sound evidence for doing so. Rather than identify where this evidence is shown in the record, however, as the law requires, the Examiner merely states that the rejection is correct because all of the elements are shown in the two references. This brings us to yet another reason why applicants' invention is patentable:

4.4 The Record Lacks Evidence to Combine Teachings

Fourthly, the record is devoid of any teaching, suggestion, or motivation to combine the pertinent teachings of Simpson and McKim. As the Board is aware, an obviousness rejection cannot be sustained, based on a combination of references, without any evidence of why a person of ordinary skill would have been motivated to combine the pertinent teachings.[11] The suggestion to make the combination must come from the prior art.[12] It is not enough to simply identify each

[11] *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998) ("When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references.").
[12] *In re Beattie*, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) ("The question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.").

claimed element in the prior art.[13] "The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with."[14]

Simpson's teachings are mainly concerned with producing a face mask that is in the shape of a pouch and that has an exhalation valve. Simpson's valve teachings are not concerned so much with showing how to make a low pressure drop valve that can remain closed under a variety of orientations as they are concerned with simply illustrating alternative valves that could be used on its pouch-shaped mask. And McKim's teachings are for providing a curved reed valve seat on a 2-cycle gasoline engine to reduce float or bounce. Nonetheless, the Examiner stated in the Office Action mailed March 26, 2003, that "[i]t would have been obvious to modify the exhalation valve of Simpson et al. to be mounted to the valve seat such that one free portion (opposite the fixed portion #14a as illustrated in fig. 3 of McKim) of the flap exhibits a curvature when viewed from the side and is pressed towards the seal surface in an abutting relationship with it when a fluid is not passing through the orifice for because it would have provided for seating quickly, effectively and without float or bounce after each opening as taught by McKim." **The Examiner has not, however, cited any authority for his view that exhalation valve flaps need to seat quickly and effectively without float or bounce after each opening. Where did the Examiner obtain this view? Where does the record show that exhalation valve flaps exhibit float or bounce?**

Although not necessary to overcome the rejection, applicants have nonetheless responded to the Examiner's unsupported position by furnishing testimony of an expert in the field of exhalation valves, John Bowers. Bowers stated that "under the airflows and pressure drops that are encountered in the filtering face mask, 'bounce or float' is not an occurring event or problem that investigators in the exhalation valve art need to deal with." Thus, although the motivation cited by the Examiner does not exist, the Examiner nonetheless totally ignores the evidence of record in the Bowers Affidavit. The Examiner's refusal to cite any prior art source in support of his views for making the combination is clear legal error. The Federal Circuit has explained at length in *In re Lee* that obviousness rejections based on combinations of references are improper when there is no

[13] *Rouffet* at 1457. ("If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability.").

evidence within the four corners of the record, to support the reasoning behind making the combination. Conclusory statements simply are not evidence.[15]

Not only has the Examiner erred by failing to supply the record with any evidence that supports his two different views for making the combination, the Examiner also has still further erred in totally disregarding the testimony of Bowers. The reviewing courts have stated on numerous occasions that it is not proper for Examiners to disregard — or substitute their viewpoint for — the evidence supplied by persons who are skilled in the technology at hand.[16] The MPEP is in accord:

> Evidence traversing rejections must be considered by the Examiner whenever present. All entered affidavits, declarations, and other evidence traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action....Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient. General statements such as 'the declaration lacks technical validity' or 'the evidence is not commensurate with the scope of the claims' without an explanation supporting such findings are insufficient.[17]

If the Examiner chooses to continue down this path, applicants request that he furnish the record with an affidavit that shows why his views for making the combination are valid. Because until

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[15] *See In re Lee*, 61 USPQ2d at 1434 ("With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation" would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. The factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority."); *see also In re Dembiczak*, 50 USPQ 1614, 1617 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence'.").

[16] *See, In re Zeidler*, 215 USPQ 490 (CCPA 1982) ("Although perception of color may, in essence, be a 'subjective' determination, we believe that an expert's evaluation in this field is entitled to more weight than that of a layman. *In re Neave*, 54 CCPA 999, 1007, 370 F.2d 961, 968, 152 USPQ 274, 279-80 (1967). Therefore, because the qualifications of Lach and the test procedures which he employed are unchallenged, the board's holding that 'a more dramatic difference in results' is required constitutes reversible error, the board having erroneously substituted its judgment for that of an established expert in the art."); *In re Fay*, 146 USPQ 47 (CCPA 1965) ("It seems to us that one as well qualified in the highly technical art of fluoride-containing halogenated compounds as Henne is shown to be is properly entitled to express his expert opinion, and that such an opinion is entitled to be given consideration with the other evidence in the case in determining whether the conclusion of obviousness is supported by the opinion of the examiner as to what the prior art teaches. For the reasons previously stated we do not think the prior art teachings furnish factual support for the examiner's opinion."); *see also In re Alton*, 37 USPQ2d 1578 (Fed. Cir. 1996) ("We do, however, hold that the examiner's final rejection and Answer contained two errors; (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case of inadequate description.").

[17] MANUAL OF PATENT EXAMINING Procedure § 2144.03, 2100-129 (August 2001).

there is evidence in the record, which evidence clearly shows that a person of ordinary skill would have combined the teachings of Simpson with McKim, the obviousness rejection based on these references cannot be properly held to constitute a *prima facie* case of obviousness.[18]

4.5 Cited References Present Evidence for Lack of Combination

Fifthly, the Simpson and McKim documents each present very good evidence of a lack of motivation to combine their respective teachings. The McKim technology was known to persons of ordinary skill before the Simpson publication. Nonetheless, Simpson did not employ the McKim technology in its flapper-style exhalation valve, even though Simpson and McKim both disclose flapper-style valves (albeit in entirely different fields). If the particular method necessary for causing the flap to be pressed towards the seal surface would have been obvious to a person of ordinary skill in making a flapper-style exhalation valve, you would have expected a person skilled in the exhalation valve art to have used that technology in a valve like Simpson's. The Board should notice that a very long time has passed since McKim's publication in 1962 and its disclosure of a curved flapper-style valve, but that particular technology did not find its way into use in the exhalation valve art at any point over this large time span. If this aspect of the present invention would have been obvious to a person of ordinary skill, the skilled artisan in the respirator art would have been expected to employ it sometime within those years. A prolonged existence of unused technology provides very good evidence of nonobviousness.[19] Simpson, which was published almost 20 years after McKim and filed more than about 12 years before the effective filing date of the present application, also did not use this technology or find it to have been obvious. Nor did any other investigator in the filtering face mask art, either prior to or after Simpson (but before applicants' invention). Thus, the prior knowledge of the McKim technology and the long time that

[18] *See Lee* at 1458. (The Federal Circuit reversed a decision of the Board because it "did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination.").

[19] *See Al-Site Corp. v. Opti-Ray Inc.*, 28 USPQ2d 1915, 1922 (E.D.N.Y. 1993) ("Second, the prior art existed for many years and yet those skilled in the art never created a hanger mechanism comparable to Al-Site's patented invention. See *id.* at 1577."); see also, *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593, 1604-05 (Fed. Cir. 1987) ("We cannot see why the district court's first set of findings did not require a conclusion that Caveney's inventions, which had for years escaped others who sought them, "would not have been obvious" under § 103; nor why Panduit and Dennison wasted research resources for years if Caveney's inventions were obvious to all throughout those years; nor how the prior art made Caveney's eminently successful inventions obvious to the court in 1984 when it had not made them obvious to skilled engineers (each more skilled than the 'ordinary mechanic' referred to in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 261, 13 L.Ed. 683 (1851)) who had been designing unsuccessful or far less successful cable ties for years when Caveney's inventions were made in the 1960's.").

has elapsed since McKim's first publication, coupled with the failure to use this technology in a flapper valve system, presents very good evidence that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.[20]

4.6 Prior Art Does Not Suggest Advantages of Applicants' Invention

Sixthly, the prior art also fails to teach or suggest the advantages that applicants' invention can provide. An invention's advantages must be considered under the "invention as whole" concept set forth in 35 USC § 103.[21] Advantages that are not appreciated by the prior art also provide very good evidence of nonobviousness.[22] In the present case, applicants' invention possesses the benefit of achieving a low pressure drop value during an exhalation while also preventing the influx of contaminants through the valve under any orientation. Simpson's valve, however, only protects to the wearer at the most critical time — during an inhalation. When a wearer of the Simpson mask inhales, the flap becomes firmly pressed against the seal surface. But when the wearer is neither inhaling nor exhaling, and has their head tilted downward, gravity can cause the flap to droop away from the seal surface. Simpson's valve may allow contaminants to enter the mask interior in this instance. To counter this problem, Simpson mounts its valve on the top of the mask body so that gravity can be used to keep the flap closed under neutral conditions. If the valve was mounted to the underside of the mask, the flap would dangle away from the seal surface. The Simpson valve, unlike applicants' invention, therefore, has limited suitable mounting positions on its mask body. And, even if it was mounted to the top of the mask body, it could still allow contaminants to enter the mask interior when the user fully tilts their head downward.

Applicants teach persons of ordinary skill how to make a low pressure drop flapper-style exhalation valve that will preclude contaminant influx under all orientations of the mask. This is achieved by the relationship between the seal surface and the flap-retaining surface and the curved configuration that is imparted to the flap and its being pressed against the seal surface under neutral conditions. Applicants' valve also does not have to be disposed on the top side of the mask. Applicants' invention, therefore, allows the valve to be attached to the mask body directly in the

[20] *See In re Ehringer*, 146 USPQ 31, 37, CCPA (1965) ("Thus over 40 years elapsed in this art prior to appellant's filing date without anyone suggesting so far as the art cited shows, a non-sag *thoriated* tungsten filament or any way of producing it.").
[21] *In re Papesch*, 137 USPQ 43 (CCPA 1963).
[22] *See, e.g., In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1989) (Advantages not appreciated by prior art.).

path of the exhale flow stream — that is, centered on the front of the mask (see Fig. 1) — so that the valve can use the full momentum of the exhaled air stream to lift the flap from the seal surface.

As indicated in paragraphs 15 and 16 of the Bowers Declaration (Exhibit B), the Simpson flap would droop open when the wearer tilts their head downward:

> My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.
>
> The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig. 2 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

The failure of Simpson to appreciate the benefits of applicants' invention and instead teach a more deficient construction further establishes the nonobviousness of applicants' invention. McKim, of course, does not address these benefits to the slightest degree because it is a reference that resides in an entirely different field and deals with entirely different problems, under entirely different conditions. In short, the prior art does not teach or suggest applicants' method, and it does not appreciate the benefits that stem from the method of the invention. Under such circumstances, Simpson and McKim would have rendered applicants' invention obvious to a person of ordinary skill within the meaning of 35 USC § 103.

4.7 Evidence of Copying Further Establishes Non-Obviousness

Seventhly, the copying of the technology of the present invention shortly after its publication further establishes the non-obviousness of the present invention. In a number of cases, the reviewing courts have relied on evidence of copying to find an invention to be not obvious to a person of ordinary skill.[23] For example, in *Specialty Composites v. Cabot Corporation,*[24] the

[23] *See e.g., All-Site Corp.*, 28 USPQ2d at 1923 ("This Court also finds that the patented hanger card was not obvious in light of the prior art because Opti-Ray's design staff copied the version depicted in Al-Site's earlier '532 patent. At

Federal Circuit stated that "[c]opying the claimed invention, rather than one in the public domain, is indicative of unobviousness."[25] As the Board is aware, secondary considerations like copying must always be considered in connection with an obviousness determination.[26] In this record is an Affidavit of Brian S. McGinley (Exhibit F), the Product Marketing Manager for the Occupational Health & Environmental Safety Products Division at 3M. Mr. McGinley has worked in the respiratory field for the past 18 years and is very familiar with the art pertaining to personal respiratory protection devices. He is also familiar with the subject matter of this patent application and has witnessed the evolution of the art in respiratory products, in particular the evolution of the exhalation valve art in filtering face masks. A reading of his Affidavit and an examination of the competitive products reveals that a number of companies have appropriated the technology that is claimed in the present application. As McGinley indicates, the developments by these companies all occurred subsequent to 3M's introduction and publication of the exhalation valve that is employed in the filtering face mask of applicants' invention. The introduction of the Louis M. Gerson product (Exhibit G) and the Moldex mask (Exhibit H) after the publication of 3M's technology, however, further establishes that person's skilled in the filtering face mask field surely did not find obvious the subject matter of the present invention.

IX. CONCLUSION

In short, applicants' invention would not have been obvious to a person of ordinary skill because the primary reference to Simpson fails to teach or suggest the basic elements of applicants' invention. Simpson does not have a curved flap, that is operatively positioned on the valve seat to be biased toward the seal surface. Simpson therefore places its exhalation valve on the top portion of its pouch-shaped mask so that gravity can keep the flap closed under neutral conditions. In this

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trial, Jimmy Vianu, Vice President of Manufacturing for Opti-Ray, was called as an adverse witness by Al-Site. Vianu conceded that he possessed copies of Al-Site's patented hanger card while designating Opti-Ray's version."); *Avia Group International, Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1564, 7 USPQ2d 1548, 1554 (Fed. Cir. 1988) (Copying is additional evidence of nonobviousness."); *Diversitech Corp. v. Century Steps, Inc.* 850 F.2d 675, 679, 7 USPQ2d 1315, 1319 (Fed. Cir. 1988) ("Copying is an indicium of nonobviousness, and is to be given proper weight."); *Windsurfing International, Inc. v. AMF Inc.*, 782 F.2d 995, 1000, 228 USPQ 562, 565 (Fed. Cir. 1986), ("copying the claimed invention, rather than one within the public domain, is indicative of non-obviousness").

[24] 6 USPQ2d 1601, (Fed. Cir. 1988).

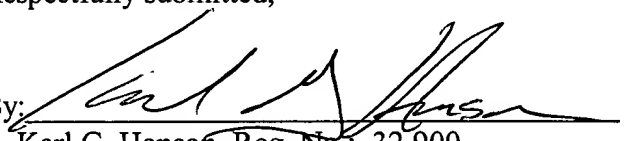
[25] *Id.* at 1608.

position, however, Simpson's valve can fog the wearer's eyeglasses, and it cannot take the best advantage of the momentum of the exhaled airflow to open the valve. Simpson fails to describe a valve that could be placed on the mask directly in front of where the wearer's mouth would be when the mask is worn. Further, the secondary reference to McKim is not applicable prior art because it is not analogous. In addition, McKim does not describe a flexible flap, and the record clearly shows that a person of ordinary skill in the exhalation valve art would not have been concerned with McKim's goals of controlling float and bounce of a reed valve. Moreover, the record is devoid of any teaching, suggestion, or motivation to combine the teachings of Simpson and McKim. There is no evidence that exhalation valve flaps exhibit problems of float or bounce — much less, seek solutions to such problems. Further, Simpson and McKim present very good evidence for a lack of motivation to combine their teachings because McKim's technology was never mentioned in Simpson or any other exhalation valve document despite it being known for many years. The prior art documents also do not teach or suggest the benefits that applicants' invention may provide. And finally, the copying of the technology claimed in the present application by a competitor further establishes that applicants' invention would not have been obvious to a person of ordinary skill within the meaning of 35 U.S.C. § 103.

For these foregoing reasons, applicants respectfully submit that the Examiner has erred in rejecting this application under 35 USC § 103. Please reverse the decision below.

Respectfully submitted,

August 25, 2003
Date

By: 
Karl G. Hanson, Reg. No.: 32,900
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3M Innovative Properties Company
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[26] *See In re Sernaker*, 217 USPQ 1, 7 (Fed. Cir. 1983) ("If, however, a patent applicant properly presents evidence relating to these secondary considerations, the board must always consider such evidence in connection with the determination of obviousness."); see also *W.L. Gore & Assoc. Inc. v. Garlock, Inc.*, 220 USPQ 303, 313 (Fed. Cir. 1983) ("As discussed more fully below, the district court erred in specifically declining to consider the objective evidence of nonobviousness."); Manual of Patent Examining Procedure 2100-90 (Feb. 2000).

APPENDIX

33. A method of making a filtering face mask, which method comprises:

(a) providing (i) a valve seat that comprises an orifice and a seal surface, wherein the orifice allows air to pass therethrough and is surrounded by the seal surface, and (ii) a single flexible flap,

(b) supporting the single flexible flap non-centrally and operatively relative to the orifice of the valve seat to form an exhalation valve, the single flexible flap being supported such that: (i) the flexible flap assumes, in its closed state, a curved profile in a cross-sectional view thereof, which the curved profile comprises a curve that extends from a first point where a first stationary portion of the flexible flap is supported on the valve seat to a second point where a second free portion of the flexible flap contacts the seal surface; (ii) the second free portion of the flap is pressed against the seal surface of the valve seat in a closed state of the exhalation valve; (iii) the second free portion of the flexible flap is held in its closed state under any orientation of the valve, at least in part, by virtue of the curved profile thereof; and (iv) the second free portion of the flexible flap represents the only free portion of the flap and can flex so as to permit exhaled air to pass through the orifice and to provide an open state of the exhalation valve to make the flexible flap out of contact with the seal surface at the second point while the first portion of the flexible flap remains essentially stationary at the first point; and

(c) attaching the exhalation vale to a mask body that is adapted to fit over the nose and mouth of a person.

35. The method of making a filtering face mask of claim 33, further comprising securing a valve cover to the valve seat that includes a flap retaining surface, the flap retaining surface being located within an internal chamber defined by a valve cover.

36. The method of making a filtering face mask of claim 35, wherein the first stationary portion of the flexible flap is held between the flap retaining surface on the valve seat and a second member that is associated with the valve cover when the valve cover is secured to the valve seat.

37. The method of making a filtering face mask of claim 36, wherein the flexible flap is secured to the valve at the first stationary portion by mechanical clamping.

38. The method of making a filtering face mask of claim 36, wherein the flexible flap can assume a curved profile, when in its closed state, that extends in from where the flexible flap contacts the second member of the valve cover to where the second portion of the flexible flap contacts the seal surface of the valve seat.

39. The method of making a filtering face mask of claim 36, wherein the flap retaining surface is oriented transversely relative to the orifice.

40. The method of making a filtering face mask of claim 39, wherein the flap retaining surface is positioned adjacent one side of the orifice.

41. The method of making a filtering face mask of claim 37, wherein the flexible flap would normally exhibit a flat configuration but is curved by virtue of the securement of the flap to the valve seat and the relative positioning and alignment between the seal surface and the flap retaining surface.

42. The method of making a filtering face mask of claim 35, wherein the flexible flap would normally exhibit a flat configuration but is curved by virtue of the securement of the flap to the valve seat and the relative positioning and alignment between the seal surface and the flap retaining surface.

44. The method of making a filtering face mask of claim 33, wherein the shape of the orifice does not correspond fully to the shape of the seal surface, and wherein the flexible flap is mounted to the valve seat in cantilever fashion.

46. The method of making a filtering face mask of claim 33, wherein the curvature of the flexible flap extends not only from the first and second points but also from a third point that

is located at where the flexible flap contacts a location on the seal surface opposite the second point.

49. The method of making a filtering face mask of claim 33, wherein the valve seat includes a flap-retaining surface that is spaced from the orifice at about 1 to 3.5 millimeters.

50. The method of making a filtering face mask of claim 33, further comprising providing the valve seat from a relatively light-weight plastic that is molded into an integral one-piece body.

55. The method of making a filtering face mask of claim 33, further comprising configuring the second free portion of the flexible flap to have a profile that when viewed from the front corresponds to the general shape of the seal surface and comprises a curve.

56. The method of making a filtering face mask of claim 55, wherein the flexible flap is configured to be 1.2 to 3 centimeters wide and about 1 to 4 centimeters long.

57. The method of making a filtering face mask of claim 55, wherein the flexible flap is configured to have a peripheral edge that includes a stationary segment that represents about 10 to 25 percent of the total circumferential edge of the flexible flap, with the remaining 75 to 90 percent of the peripheral edge being free to be lifted from the seal surface.

58. The method of making a filtering face mask of claim 33, wherein the flexible flap is supported on the valve such that exhaled air is deflected downward during an exhalation when the filtering face mask is worn on a person.

59. The method of making a filtering face mask of claim 33, wherein the mask body is cup-shaped and includes a filtering material and a shaping layer for providing structure to the mask.

64. The method of making a filtering face mask of claim 33, wherein the exhalation valve is attached to the mask body such that the second free portion of the flexible flap resides beneath the stationary portion when the mask is worn on a person.

65. A method of making a filtering face mask, which method comprises:

(a) providing (i) a valve seat that comprises an orifice and a seal surface, wherein the orifice allows air to pass therethrough and is surrounded by the seal surface, and (ii) a single flexible flap;

(b) supporting the single flexible flap non-centrally and operatively relative to the orifice of the valve seat to form an exhalation valve, the single flexible flap being supported such that: (i) the flexible flap has, in its closed state, an imposed curved profile in a cross-sectional side view thereof, which imposed curved profile extends from a first point where a stationary portion of the flexible flap is supported on the valve seat to a second point where a free portion of the flexible flap contacts the seal surface; (ii) the free portion of the flexible flap is pressed towards the seal surface of the valve seat in a closed state of the exhalation valve under any orientation thereof; (iii) the free portion of the flexible flap is held in the closed state under any orientation of the valve, at least in part, by virtue of the imposed curved profile thereof; and (iv) the free portion of the flexible flap represents the only free portion of the flap and can flex away from the seal surface so as to permit exhaled air to pass through the orifice and to provide an open state of the exhalation valve to make the flexible flap out of contact with the seal surface at the second point while the stationary portion of the flexible flap remains essentially stationary at the first point; and

(c) attaching the exhalation valve to a mask body that is adapted to fit over the nose and mouth of a person, the exhalation valve being attached to the mask body such that the first point is disposed above the second point when the mask is viewed from the front in an upright position.

66. A method of making a filtering face mask, which method comprises:

(a) providing (i) a valve seat that comprises an orifice, a seal surface, and a flap-retaining surface wherein the orifice allows air to pass therethrough and is surrounded by the seal surface, (ii) a single flexible flap, and (iii) a valve cover that is joined to the valve seat;

(b) supporting the single flexible flap non-centrally and operatively relative to the orifice of the valve seat to form an exhalation valve, the single flexible flap being supported such

that: (i) the flexible flap has, in its closed state, an imposed curved profile in a cross-sectional side view thereof, which imposed curved profile extends from a first point where a stationary portion of the flexible flap is supported on the valve seat to a second point where a free portion of the flexible flap contacts the seal surface; (ii) the free portion of the flexible flap is pressed towards the seal surface of the valve seat in a closed state of the exhalation valve under any orientation thereof; (iii) the free portion of the flexible flap is held in the closed state under any orientation of the valve, at least in part, by virtue of the imposed curved profile thereof; (iv) the free portion of the flexible flap represents the only free portion of the flap and can flex away from the seal surface so as to permit exhaled air to pass through the orifice and to provide an open state of the exhalation valve to make the flexible flap out of contact with the seal surface at the second point while the stationary portion of the flexible flap remains essentially stationary at the first point; and (v) the stationary portion of the flexible flap is held between the flap retaining surface of the valve seat and a second surface that is associated with the valve cover when the valve cover is secured to the valve seat, wherein the imposed curved profile extends at least from where the flexible flap contacts the second surface associated with the valve cover to where the second portion of the flexible flap contacts the seal surface of the valve seat when the exhalation valve is in its closed state; and

(c) attaching the exhalation valve to a mask body that is adapted to fit over the nose and mouth of a person, the exhalation valve being attached to the mask body such that the first point is disposed above the second point when the mask is viewed from the front in an upright position.